MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNEIL

McNEIL CONSUMER PROD... COMPANY
FORT WASHINGTON

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Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

Individual Safety Report

3128140-8-00-01

A. Patient information

1. Patient identifier	2. Age at time of event: / Date of birth:	3. Sex	4. Weight
Case 183 In confidence	or 18 mo	( )female (X)male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(x) death unknown (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event: unknown (mo/day/yr)

4. Date of this report: 08/27/98 (mo/day/yr)

5. Describe event or problem

Literature report (Am J Emerg Med 1997;16(5):443-497) from Annual Report of the American Association of Poison Control Centers TESS database of human exposure cases reported by 66 participating centers during 1997. Case 183, an 18 month old was admitted to the hospital w/persistent NAUSEA, VOMITING AND DIARRHEA. The child was admitted to the ICU & was initially treated w/IV & oral N-acetylcysteine. Plasma acetaminophen of 46 ug/mL from blood drawn approx 28h after ADM established the diagnosis of acetaminophen intoxication. Three days after Adm his condition worsened & he was placed on a ventilator. His liver enzymes became markedly elevated (LIVER FUNCTION TESTS ABNORMAL) & he developed renal failure (KIDNEY FAILURE). By the 5th hospital day pt was receiving lipids w/hyperalimentation & antibiotics for a possible pulmonary INFECTION. The child soon developed ARDS (RESPIRATORY DISORDER) became very unstable & was placed on extracorporeal membrane oxygenation. Despite supportive treatment he died(DEATH) 11 days after Adm. No further info was provided.

6. Relevant tests/laboratory data, including dates

acetaminophen level 28 hrs after admission=46 ug/mL; liver enzymes-markedly elevated

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

C. Suspec

1. Name (give labeled strength & mfr/labeler, if known)

#1 unknown acetaminophen product

#2

2. Dose, frequency & route used

#1 unknown dose, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown

#2

4. Diagnosis for use (indication)

#1 therapeutic error

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 Unknown

#2

7. Exp. date (if known)

#1 Unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

( ) foreign
( ) study
(X) literature
( ) consumer
(X) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 08/27/98

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

NAUSEA VOMIT DI LIVER FUNC ABNO
KIDNEY FAILURE INFECTION
RESPIRATORY DIS OVERDOSE
DEATH

9. Mfr. report number

1026341A

E. Initial reporter

1. Name, address & phone #

Toby L. Litovitz, MD
Amer. Assoc. of Poison Control Centers
3201 New Mexico Avenue, Suite 310
Washington D.C. 20016

SEP 1 0 1998

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.